UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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Donald Martin Meyer, Manishkumar H. Bhagat, and Dustin L. Lineweber, *Individually and on Behalf of All Others Similarly Situated*,

Plaintiffs,

-against-

Organogenesis Holdings Inc., Gary S. Gillheeney, Sr., and David C. Francisco,

Defendants.
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MEMORANDUM & ORDER
21-CV-06845 (DG) (MMH)

DIANE GUJARATI, United States District Judge:

On December 10, 2021, Gergely Somogyi commenced this action asserting claims pursuant to the Securities Exchange Act of 1934 (the "Exchange Act"). *See* ECF No. 1. By Order dated August 25, 2022, Donald Martin Meyer was appointed lead plaintiff. *See* ECF No. 25. On October 24, 2022, Lead Plaintiff Meyer and named Plaintiffs Manishkumar H. Bhagat and Dustin L. Lineweber (collectively, "Plaintiffs") filed the operative Amended Complaint against Defendants Organogenesis Holdings Inc. ("Organogenesis" or the "Company"), Gary S. Gillheeney, Sr., an Organogenesis Director and the Company's President and Chief Executive Officer, and David C. Francisco, Organogenesis's Chief Financial Officer (together with Defendant Gillheeney, the "Individual Defendants," and collectively with Defendant Gillheeney and Defendant Organogenesis, "Defendants"). *See generally* Amended Complaint ("Am. Compl."), ECF No. 34.

The Amended Complaint contains approximately 426 paragraphs and spans 156 pages. The Court has considered all allegations contained in the Amended Complaint, including those not expressly referenced herein.

In substance and in summary, Plaintiffs allege in the Amended Complaint that from August 10, 2020 through August 9, 2022 (the "Class Period"), Defendants engineered a "spread" between the cost Organogenesis charged physicians for two skin substitute products – Affinity and PuraPly XT – and the amount that certain Medicare Administrative Contractors reimbursed physicians for these products, and that Defendants aggressively marketed this spread to physicians in order to artificially inflate the Company's revenues.[1] Plaintiffs further allege that, during the Class Period, Defendants made a series of materially false or misleading statements and omissions of material fact in the Company's press releases, earnings calls with investors, and filings with the U.S. Securities and Exchange Commission ("SEC"), which statements and omissions concealed from the market the truth about the source and sustainability of the Company's revenues. Plaintiffs allege that once Defendants' marketing scheme ended, revenues for Affinity declined and investors suffered losses when the Company's stock price declined.

The Amended Complaint is brought in two Counts. Count I asserts violations of Section 10(b) of the Exchange Act ("Section 10(b)") and SEC Rule 10b-5 ("Rule 10b-5") against all Defendants. *See* Am. Compl. ¶¶ 420-22. Count II asserts violations of Section 20(a) of the Exchange Act against the Individual Defendants. *See* Am. Compl. ¶¶ 423-26.

Plaintiffs assert that they "bring this action on their own behalf and as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a Class consisting of all persons and entities who purchased the common stock of Organogenesis from August 10, 2020 through August 9, 2022, inclusive, and were damaged thereby," with certain exclusions. *See* Am. Compl. ¶ 406.

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[1] Plaintiffs allege that the Class Period runs from the reporting of Organogenesis's 2Q2020 results on August 10, 2020 through the release of its 2Q2022 results on August 9, 2022. *See* Am. Compl. ¶ 77.

Plaintiffs seek, *inter alia*, "compensatory damages in favor of Plaintiffs and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' alleged wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon" and costs and expenses. *See* Am. Compl. at 155.

Pending before the Court is Defendants' Motion to Dismiss the Amended Complaint pursuant to Rules 8(a), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure and Section 101(b) of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b)(2). *See* Defendants' Notice of Motion to Dismiss the Amended Complaint, ECF No. 52; Declaration of Rachel L. Kerner in Support of Defendants' Motion to Dismiss the Amended Complaint, ECF No. 53 ("Kerner Declaration");[2] Defendants' Memorandum of Law in Support of Defendants' Motion to Dismiss the Amended Complaint ("Defs.' Br."), ECF No. 54; Defendants' Reply in Support of Defendants' Motion to Dismiss the Amended Complaint ("Defs.' Reply"), ECF No. 56. Plaintiffs oppose Defendants' motion. *See* Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Amended Complaint ("Pls.' Br."), ECF No. 55.

For the reasons set forth below, Defendants' Motion to Dismiss is granted and the Amended Complaint is dismissed.

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[2] Together with the Kerner Declaration, Defendants submitted eight exhibits. *See* ECF Nos. 53-1 to 53-8. In referring to exhibits, the Court uses the numbers assigned to the exhibits in the Kerner Declaration. In citing to exhibits, the Court refers to the pagination generated by the Court's electronic case filing system ("ECF"), rather than to the exhibits' internal pagination. All other citations are to the cited document's internal pagination.

BACKGROUND

I. Factual Background[3]

A. Organogenesis's Business

As alleged in the Amended Complaint, Organogenesis is a publicly-traded regenerative medicine company engaged primarily in the development, manufacture, and commercialization of solutions for the "Advanced Wound Care" and "Surgical & Sports Medicine" markets. *See* Am. Compl. ¶ 33. Plaintiffs allege that the Company sells its Advanced Wound Care and Surgical & Sports Medicine products to physicians' offices, wound care centers, government facilities, Ambulatory Surgical Centers ("ASCs"), and hospitals. *See* Am. Compl. ¶ 37. Plaintiffs allege that the Company sells skin substitute products, including Affinity, which consists of a tissue graft made from human amniotic cells, and PuraPly XT, which consists of a porcine collagen sheet coated with an antimicrobial agent. *See* Am. Compl. ¶¶ 63-64.

1. Medicare Reimbursement

Plaintiffs allege that as a medical device manufacturer, Organogenesis's growth and profitability depends on its ability to obtain reimbursement for its products by Medicare and private insurers. *See* Am. Compl. ¶ 69. Plaintiffs further allege that, during the Class Period, Medicare was the primary, if not exclusive source of reimbursement for Organogenesis's newest and most profitable products, including Affinity and PuraPly XT. *See* Am. Compl. ¶ 71.

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[3] The following facts, which are viewed in the light most favorable to Plaintiffs, are drawn from the Amended Complaint and from certain documents incorporated by reference in the Amended Complaint or integral to the Amended Complaint, as to which there is no dispute regarding authenticity, accuracy, or relevance.

The Amended Complaint is replete with bolded and italicized phrases. The Court omits all bolded and italicized formatting when quoting allegations contained in the Amended Complaint.

Plaintiffs allege that in the context of Medicare reimbursement, the reimbursement for Organogenesis's products depends on the treatment setting where the product is used. *See* Am. Compl. ¶ 72.

Plaintiffs allege that generally speaking, in the physician office setting, skin substitutes such as those sold by Organogenesis are reimbursed by Medicare using an average sales price ("ASP") plus 6% formula set by the Centers for Medicaid and Medicare Services ("CMS"), with the ASP updated quarterly based on data reported by the manufacturer and published in the CMS quarterly ASP Drug Pricing File. *See* Am. Compl. ¶¶ 7, 77. Plaintiffs allege that, in contrast, in the hospital outpatient and ASC settings, Medicare reimbursement for Organogenesis's products is "bundled" with the payment for the procedure and the payment rate for these procedures does not vary based on which device is used, so higher-cost products like Affinity or PuraPly may be reimbursed at less than their cost. *See* Am. Compl. ¶ 73. Plaintiffs allege that in these settings, in certain instances, a product may be granted pass-through reimbursement status ("pass-through status") by CMS. *See* Am. Compl. ¶ 73. Plaintiffs allege that if pass-through status is granted, reimbursement for the product is equal to the ASP plus 6% for two to three years until the grace period ends. *See* Am. Compl. ¶ 73.

Plaintiffs allege that during the Class Period, PuraPly XT did not have an ASP and Affinity only had an ASP for 3Q2021 and then again for 1Q2022 and 2Q2022. *See* Am. Compl. ¶ 77. Plaintiffs allege that in the absence of an ASP, the reimbursement amount for these products sold in the physician office setting was determined by the regional Medicare Administrative Contractors ("MACs"), which often reimbursed physicians in amounts far in excess of the cost charged by Organogenesis to the treating physician. *See* Am. Compl. ¶¶ 1, 78. Moreover, Plaintiffs allege that the MACs did not require the physician to submit an actual,

physical invoice from Organogenesis in order to be reimbursed for using the Company's products, and accordingly, the MACs did not have any independent record to ferret out inflated claims. *See* Am. Compl. ¶ 108.[4]

2. Expiration of PuraPly and PuraPly AM's Pass-Through Status

Plaintiffs allege that prior to the Class Period, Organogenesis relied on the temporary pass-through status of two Organogenesis products – PuraPly and PuraPly AM – as one of the primary drivers of its sales. *See* Am. Compl. ¶¶ 90-96. Specifically, Plaintiffs allege that in 2015, CMS approved PuraPly and PuraPly AM for pass-through status for the hospital outpatient and ASC settings and that the Company maintained this advantageous pass-through status for both PuraPly and PuraPly AM for approximately two years, until it expired on December 31, 2017. *See* Am. Compl. ¶ 90. Plaintiffs allege that during this period, from 2015 to 2017, PuraPly and PuraPly AM's favorable pass-through status more than doubled Organogenesis's net revenue but, despite this extraordinary year-over-year growth in net revenue, Organogenesis operated at a net loss for 2015, 2016, and 2017. *See* Am. Compl. ¶ 91. Plaintiffs further allege that as soon as PuraPly and PuraPly AM lost pass-through status, Organogenesis's reported net losses increased dramatically. *See* Am. Compl. ¶ 92. Plaintiffs allege that on March 23, 2018, the pass-through status for both PuraPly and PuraPly AM was restored effective October 1, 2018 through September 30, 2020. *See* Am. Compl. ¶ 93. Plaintiffs allege that with pass-through status restored, Organogenesis's "dismal financial results improved." *See* Am. Compl. ¶ 94.

Plaintiffs allege, however, that notwithstanding the Company's reported success in 2019,

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[4] Plaintiffs also allege that "Organogenesis was required to comply with healthcare fraud, waste, and abuse laws with respect to the sales and marketing of its products that received reimbursement under Medicare," *see* Am. Compl. ¶ 79, and Plaintiffs include certain allegations regarding various laws and regulations, *see* Am. Compl. ¶¶ 79-89.

the market was well aware of the impending expiration of PuraPly and PuraPly AM's pass-through status and was bracing for the potential negative impact this would have on the Company's sales. *See* Am. Compl. ¶ 97. Plaintiffs allege that Defendants sought to assuage investors' concerns by highlighting the Company's shift in focus to the physician office channel – which was not subject to bundled pricing – and by touting the launch of PuraPly XT and re-launch of Affinity. *See* Am. Compl. ¶ 99. Plaintiffs allege that in February 2020, Organogenesis launched PuraPly XT and in late 1Q2020, Organogenesis relaunched Affinity after an approximately one year hiatus and began rolling Affinity out to physician offices. *See* Am. Compl. ¶ 99.[5]

Plaintiffs allege that Affinity and PuraPly XT did not have pass-through status during the Class Period and that due to these products' high cost and inclusion in Medicare's bundled reimbursement structure, it was extremely difficult for Organogenesis's sales representatives to sell Affinity or PuraPly XT in outpatient hospital and ASC settings, where providers could lose money if they chose to use these products. *See* Am. Compl. ¶ 75. Plaintiffs allege that therefore, the success of Affinity and PuraPly XT – and by extension, the Company's strategy of expanding into the physician office channel – depended on the ability of the Organogenesis's sales force to generate sales in physician offices. *See* Am. Compl. ¶ 75.

B. Alleged Reimbursement Scheme

Plaintiffs allege that during the Class Period, Organogenesis's revenue growth was the product of a reimbursement marketing scheme perpetrated by the Company's sales force – under

[5] Plaintiffs allege that Organogenesis had previously marketed Affinity prior to 2019 but withdrew it from the market in 1Q2019 just before an ASP was established, with Organogenesis claiming that this was due to purported production issues. *See* Am. Compl. ¶ 7.

the direction of senior management – with respect to Affinity and PuraPly XT. *See* Am. Compl. ¶ 107. Specifically, Plaintiffs allege that the Company's sales team "aggressively" and "illegally" marketed the "spread" between the amount reimbursed by the MACs and the amount charged by Organogenesis, which allowed Organogenesis to temporarily inflate its sales and give investors a false impression of the Company's business. *See* Am. Compl. ¶ 78.

In describing this alleged scheme, Plaintiffs rely on, *inter alia*, the accounts of thirteen former employees ("FEs") of the Company, whose former roles include "Tissue Regeneration Specialist," "Tissue Regeneration Associate," "Regional Sales Manager," "marketing executive," "Tissue Regeneration Sales Associate," "Tissue Regeneration Sales Specialist," and "Tissue Regeneration Sales Assistant." *See* Am. Compl. ¶¶ 38-50; *see also* Am. Compl. at 1. Plaintiffs allege that Organogenesis encouraged physicians to submit claims for invoice amounts equal to, or higher than the regional MAC reimbursement rates, while at the same time, Organogenesis set the non-public cost of these products substantially less than the amount reimbursed by the MACs. *See* Am. Compl. ¶ 109 (referencing accounts of FE-1, FE-2, FE-3, FE-4, FE-6, FE-7, FE-8, FE-12, and FE-13). Plaintiffs allege that pricing for Affinity and PuraPly XT was set by the Pricing Committee, which included Defendant Gillheeney. *See* Am. Compl. ¶ 153 (referencing statement by FE-9). Plaintiffs allege that the prices set by the Pricing Committee for Affinity and PuraPly XT and the amount MACs reimbursed for these products created what was referred to internally at the Company as, *inter alia*, the "spread." *See* Am. Compl. ¶ 153. Plaintiffs allege that during the Class Period, the reimbursement amount paid by certain MACs allowed physicians to make as much as $3,800 with a single application of Affinity, and as much as $5,410 for a single application of PuraPly XT. *See* Am. Compl. ¶ 154.

Plaintiffs allege that the Company's sales team, under the direction of Organogenesis's

management, marketed the temporary reimbursement spread for Affinity and PuraPly XT to generate sales, thereby inflating the Company's revenues to unsustainable levels. *See* Am. Compl. ¶ 166 (referencing accounts of FE-1, FE-2, FE-6, and FE-7). Plaintiffs allege that Organogenesis management sanctioned sales representatives' marketing of the reimbursement spread for Affinity and PuraPly XT and pushed the Company's sales force to sell these products while they lacked an ASP. *See* Am. Compl. ¶ 183. Plaintiffs allege that Organogenesis's sales strategy was to focus on MACs that reimbursed for products without an ASP and that senior management from Gillheeney "on down" knew of this strategy. *See* Am. Compl. ¶ 190 (referencing account of FE-9). Plaintiffs allege that it was known that sales would decline once Affinity and PuraPly XT were eventually reimbursed at an ASP-based rate. *See* Am. Compl. ¶ 191 (referencing statement by FE-1). Plaintiffs further allege that, officially, Organogenesis sales representatives were not supposed to market products based on the reimbursement spread, but in practice, it was "pretty clear what the goal was," *see* Am. Compl. ¶ 187 (quoting statement by FE-8), and that sales representatives received under the radar direction from Organogenesis management that they should sell Affinity and PuraPly XT on the spread while there was no ASP, *see* Am. Compl. ¶ 188 (referencing account of FE-4).[6]

C. Alleged Materially False or Misleading Statements and Omissions of Material Fact

Plaintiffs allege that during the Class Period, Defendants made a series of materially false or misleading statements and omissions of material fact in Organogenesis's press releases, earnings calls with investors, and SEC filings. *See* Am. Compl. ¶ 240. Plaintiffs allege that

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[6] Plaintiffs also allege that the Company engaged in other unsustainable practices to inflate sales of Affinity and PuraPly XT, including using "odd-even pricing" and offering reimbursement guarantees through the Company's "Assurance Program." *See* Am. Compl. ¶¶ 194-99.

Defendants misrepresented or omitted material information concerning: (1) Organogenesis's practice of marketing the reimbursement spread for Affinity and PuraPly XT and the impact that this unsustainable practice had on the Company's reported revenue; (2) the factors contributing to the Company's sales growth and apparent ability to offset the loss of revenue from the expiration of PuraPly's pass-through status; (3) the impact that changes in reimbursement for Affinity had on the Company's ability to generate sustainable sales growth; (4) the Company's compliance with healthcare laws and regulations intended to prevent fraud, waste, and other abusive practices; and (5) the Company's ability to compete on the basis of the clinical benefits of its products, as opposed to the reimbursement physicians received for using the Company's products. *See* Am. Compl. ¶ 240.[7]

In the Section of the Amended Complaint titled "DEFENDANTS' MATERIALLY FALSE OR MISLEADING STATEMENTS AND OMISSIONS OF MATERIAL FACT," which spans over 30 pages, Plaintiffs set forth allegations regarding statements made by Defendants on August 10, 2020; September 16, 2020; November 9, 2020; March 16, 2021; May 10-11, 2021; August 9, 2021; September 20, 2021; November 9, 2021; February 18, 2022; March 1, 2022; and May 10, 2022, including the following statements:[8]

- August 10, 2020 – Defendant Gillheeney's statements during an earnings call that: "we launched PuraPly XT and Affinity in the midst of a crisis and both have exceeded our expectations" and the "office space business grew even faster than we thought," *see* Am. Compl. ¶ 242; regarding PuraPly XT, "[w]e thoughtfully launched it in only certain regions of the country, and it's performing above our expectations at this point," *see* Am. Compl. ¶ 244; regarding Affinity, "we've strategically launched it in certain areas of the

[7] Plaintiffs also allege that Defendants' failure to disclose the "known uncertainty in the sustainability of its revenues driven by its Medicare Reimbursement Scheme for Affinity and PuraPly XT in the Company's 10-Ks and 10-Qs filed during the Class Period violated Item 303 and Section 10(b) of the Exchange Act." *See* Am. Compl. ¶ 351.

[8] The Court has considered all of the alleged actionable statements contained in the Amended Complaint, including those statements – and portions of statements – not explicitly referenced herein.

country in the office only," "we've been able to add additional customers at a very rapid rate," "the product is selling extremely well," and "[i]t's exceeded our expectations at this point in time," *see* Am. Compl. ¶ 245; and "[w]e are clearly taking share in the office," *see* Am. Compl. ¶ 246.

- August 10, 2020 – Defendant Gillheeney's statement in an Organogenesis press release that "[d]uring the second quarter, we grew our customer base, drove customer and clinician adoption deeper into existing accounts and leveraged the strong demand for our PuraPly and amnion products, particularly in the office channel." *See* Am. Compl. ¶ 241.

- August 10, 2020 – Defendants' statement in an Organogenesis Form 10-Q that "[s]everal factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions." *See, e.g.*, Am. Compl. ¶ 251.

- September 16, 2020 – Defendant Gillheeney's statements during the Morgan Stanley Global Healthcare Conference that: "one of the reasons we've moved into the office and really put a major emphasis on the office-based setting is it's a different reimbursement model than the outpatient model. So it not only diversifies the revenue risk, it diversifies the reimbursement risk, and it's also a very, very large market. So in this space, it's reimbursement that you typically will focus on and want to make sure that your products are well positioned and well reimbursed," *see* Am. Compl. ¶ 254; and "we are a very compliant company, and we are the gold standard of compliance, and that's not my opinion. That's what I hear back from the financial community when they do diligence on our company and that's just – that's who we are," "as some of our competitors have stumbled, we have stood out," and "folks look to us for solving their wound care problems and making sure that we're conducting ourselves and conducting business in their clinics in a very compliant way. It's important in this space," *see* Am. Compl. ¶ 256.

- November 9, 2020 – Defendant Gillheeney's statements during an earnings call that: Affinity "was the largest contributor to growth again in Q3, driven by the differentiated features of the product that our clinical customers value and positive reimbursement in the office channel," *see* Am. Compl. ¶ 263; "[c]linicians continue to value the product's clinical value, and we continue to see growth in the number of accounts that are utilizing PuraPly, aided in part by the introduction of new sizes and the introduction of our XT line extension, which is selling extremely well," *see* Am. Compl. ¶ 264; "we believe our operating and financial performance is a direct result of the strong execution of our growth and profitability strategy and the dedication of our employees to our customers and the patients they serve," *see* Am. Compl. ¶ 265; and "we've also accelerated our office growth strategy with PuraPly," *see* Am. Compl. ¶ 266.

- March 16, 2021 – Defendant Gillheeney's statements during an earnings call that: with respect to PuraPly, "we've positioned the product differently this time coming off of

pass-through" and "launched 5 new PuraPly product and line extensions in 2020," which "contributed to our ability to drive strong sales performance in the fourth quarter," *see* Am. Compl. ¶ 276 (alteration accepted); and "[o]ur product, Affinity, is the only living amnion in the space, so it's a bit unique. So from a competitive perspective, we don't see any product out there that's really challenging it from a technology perspective. And the efficacy that we're hearing from the field is very strong for the product as well," *see* Am. Compl. ¶ 277.

- March 16, 2021 – Defendants' statement in an Organogenesis Form 10-K that: "the increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product" and "the continued increase in PuraPly revenue in the year ended December 31, 2020 was due to the expanded sales forces, expanded product offerings, and increased sales to existing and new customers." *See* Am. Compl. ¶ 283 (alterations accepted).

- May 10, 2021 – Defendant Gillheeney's statements on an earnings call that: "[o]ur better-than-expected growth in Q1 reflects a continuation of the key drivers of our growth strategy, including the benefits of our comprehensive portfolio of products, the investments that we've made to broaden our reach by expanding our sales force and the strong execution of our commercial strategy, focusing on leveraging multiple channels, new product introductions and brand loyalty," *see* Am. Compl. ¶ 286; "consistent with what we've experienced in the last quarter, PuraPly's performance in the first quarter further validates the benefits of these strategic initiatives," "we believe [our Q1 results] reflects the strong execution of the strategy to navigate the loss of PuraPly pass-through status and the corresponding headwinds related to this change in reimbursement," and "[c]linicians continue to value the product's differentiation, and we continue to see the number of accounts utilizing PuraPly, aided in part by strong sales of our 5 new products and line extensions introduced in 2020," *see* Am. Compl. ¶ 288; "[w]e have been working on penetrating the office market primarily with channel-specific product offerings" and "continue to expand the number of customers in the office channel, and we are seeing increasing utilization of our products from existing customers," *see* Am. Compl. ¶ 289; and "we definitely feel that there's a margin -- a market shift in our favor," *see* Am. Compl. ¶ 291.

- May 10, 2021 – Defendant Francisco's statement on the same earnings call that "it's just the strength in PuraPly over the last 2 quarters really gives us the confidence to increase that by quite a bit and strength of the amnions as well." *See* Am. Compl. ¶ 290.

- August 9, 2021 – Defendant Gillheeney's statements during an earnings call that: "we're pleased with the strong demand for these products given the amniotic portfolio's high degree of efficacy that clinicians and their patients truly value in the market," *see* Am. Compl. ¶ 299; and, with respect to PuraPly products, "[t]his strong growth further validates the clinical utility of our brand and our strategic positioning of the product family," *see* Am. Compl. ¶ 300.

- September 20, 2021 – Defendant Gillheeney's statement at the Oppenheimer Fall Healthcare Life Sciences & MedTech Summit that "in the medium-term, our growth strategy reflects our continued ramp of Affinity which we've launched nationally in Q3. Our execution on the office setting strategy, we continue to penetrate that side of care. And that side of care has allowed us to expand the market, really moving clinicians that traditionally did basic wound care that never did advanced wound care in their office are now starting to do that with our help. We've built our commercial infrastructure, our portfolio offerings and some of our services to support that office-based business, and we are seeing the expansion of the market as a result." *See* Am. Compl. ¶ 309.

- November 9, 2021 – Defendant Gillheeney's statements during an earnings call that "sale of our amniotic products were essentially flat in the third quarter," *see* Am. Compl. ¶ 314; and "[o]ur Q4 ASP submission was impacted by a filing error, which initially resulted in an incorrect rate issued by CMS and ultimately resulted in Affinity not having a published rate for the fourth quarter. However, we are confident that the nationally published rate will be reinstated on January 1, 2022," *see* Am. Compl. ¶ 316.

- November 9, 2021 – Defendant Gillheeney's statement in an Organogenesis press release that "[o]ur year-to-date performance and progress against our strategic priorities is a direct result of the strength of our organization and the dedication of our employees." *See* Am. Compl. ¶ 312.

- February 18, 2022 – Defendant Gillheeney's statement during the SVB Leerink Global Healthcare Conference 2022 that Affinity's reimbursement issues were "clearly behind us from a company and from a customer perspective" and "we believe Affinity is appropriately priced in the market." *See* Am. Compl. ¶ 325.

- March 1, 2022 – Defendant Gillheeney's statements during an earnings call that: "our comprehensive portfolio of products is a key competitive advantage for Organogenesis and continues to be a primary driver of our impressive growth in recent years," *see* Am. Compl. ¶ 328; "PuraPly is back with proven clinical outcomes is highly efficacious in the early stages of wound healing and therefore, remains a key component to the healing algorithm from our clinicians and patients," *see* Am. Compl. ¶ 329; and, with respect to the Company's amniotic products, "[w]e did see a slight decline as expected in the first month and then started to grow as expected and actually better than expected. So we put a lot of time and focus on the amniotic portfolio in Q4, and it helped in exceeding our expectations," *see* Am. Compl. ¶ 331.

- May 10, 2022 – Defendant Gillheeney's statements during an earnings call that: "[o]ur strategy to introduce new products and line extensions have enabled access to multiple sites of care and physician specialties and continue to drive strong demand for the PuraPly brand," *see* Am. Compl. ¶ 339; with respect to the performance of amniotic products, "[t]hese results were largely in line with our expectation and reflect the impact of Omicron on our national launch of Affinity," *see* Am. Compl. ¶ 340; and "[t]he trends that we're seeing now are very positive. We're adding new accounts in multiple sites of care for the product and the sales trends over the last 4 to 5 weeks have actually been

quite strong," *see* Am. Compl. ¶ 341.

- May 10, 2022 – Defendant Gillheeney's statement in an Organogenesis press release that "Organogenesis is well-positioned to manage through the near-term operating environment challenges and achieve strong, long-term growth." *See* Am. Compl. ¶ 337.

D. Scienter-Related Allegations

The Amended Complaint includes various allegations purporting to establish Defendants' scienter.

Plaintiffs allege that "Defendant Gillheeney personally profited by selling millions in Organogenesis common stock while the Company's stock price was artificially inflated by his repeated false or misleading statements, supporting an inference that Gillheeney acted with scienter in making these statements to investors." *See* Am. Compl. ¶ 353. Specifically, Plaintiffs allege (1) that in February 2021, Defendant Gillheeney sold 397,900 shares of Organogenesis common stock for total proceeds of approximately $5.3 million, *see* Am. Compl. ¶ 354; (2) that in July 2021, Defendant Gillheeney sold an additional 300,000 shares of Organogenesis common stock for total proceeds of $4.3 million, *see* Am. Compl. ¶ 357; and (3) that between May 13, 2022 and June 3, 2022, Defendant Gillheeney sold 1,250,000 shares for total proceeds of more than $7.2 million, *see* Am. Compl. ¶ 361. Plaintiffs allege that Defendant Gillheeney's February 2021, July 2021, and May-June 2022 sales were made pursuant to Rule 10b5-1 trading plans entered into in August 2020, June 2021, and March 2022, respectively. *See* Am. Compl. ¶¶ 356, 359, 363.

Plaintiffs also allege that the Company profited from the alleged misstatements and omissions through a secondary public offering (the "SPO") in which Organogenesis raised gross proceeds of $64.7 million and net proceeds of $59 million and that the SPO "supports an inference of Organogenesis's corporate scienter." *See* Am. Compl. ¶ 365; *see also* Am. Compl.

¶¶ 128-30.

Plaintiffs allege that the Individual Defendants' own statements – such as Defendant Gillheeney's statements that "[w]e thoughtfully launched [PuraPly XT] in only certain regions of the country," and "one of the reasons we've moved into the office and really put a major emphasis on the office-based setting is it's a different reimbursement model than the outpatient model," *see* Am. Compl. ¶ 367 – and the Individual Defendants' roles at the Company strongly suggest that each had detailed knowledge of or access to information concerning the alleged reimbursement scheme and if Defendants issued their statements without such knowledge, Defendants were reckless in failing to investigate the subject matter of their statements. *See* Am. Compl. ¶ 373.

In the Amended Complaint, Plaintiffs assert that the FE accounts further demonstrate Defendants' scienter, pointing to, for example, the allegations based on FE accounts that "the Organogenesis Pricing Committee, comprised of Organogenesis senior management including Defendant Gillheeney, formulated and oversaw the Company's pricing strategy;" that "Organogenesis management oversaw and encouraged the Company's sales representatives to market the spread of Affinity and PuraPly XT by supplying iPads with an application that calculated physicians' reimbursement profits and by training its sales representatives on the application;" that "Organogenesis management also participated in discussions regarding the reimbursement for Affinity and PuraPly XT during national and regional sales meetings, and urged its sales representatives to sell the products before an ASP was established;" that "Organogenesis senior management, including Defendants Gillheeney and Francisco, had full access to Power BI which showed sales and revenue data by geographic region;" and that "Organogenesis management acknowledged and communicated internally to its sales

representatives that Organogenesis could no longer market the reimbursement spread once Affinity and PuraPly XT received an ASP, which would put an end to their favorable reimbursement." *See* Am. Compl. ¶¶ 375-79.

Plaintiffs allege that Organogenesis management provided a top-down directive to its sales representatives to sell on the spread and that when sales representatives refused to comply with this directive, or reported their concerns to the Company's management and compliance department, they were retaliated against and silenced. *See* Am. Compl. ¶¶ 380-81. Plaintiffs allege that Defendants' systematic silencing of employees who reported the Company's illegal marketing activities supports an inference that Defendants knew or recklessly disregarded that Organogenesis's sales force was engaged in the Medicare reimbursement scheme. *See* Am. Compl. ¶ 383.

Plaintiffs allege that on May 10, 2019, during the 1Q2019 earnings call, Defendant Gillheeney told market analysts that Affinity was being withdrawn from the market until the Company could contract with another manufacturer and bring Affinity production to commercial scale – likely 1Q2020, but, unbeknownst to the market, the true reason for suspending Affinity's sales was that Affinity was going to receive a low ASP. *See* Am. Compl. ¶¶ 384-85; *see also* Am. Compl. ¶¶ 387-88. Plaintiffs assert that the fact that Defendant Gillheeney misstated the true reasons for Affinity being suspended from the market supports a strong inference of Defendants' scienter to perpetuate their scheme. *See* Am. Compl. ¶ 386.

Plaintiffs allege that the knowledge or recklessness of Defendants Gillheeney and Francisco concerning Defendants' false or misleading statements is imputed to Organogenesis, *see* Am. Compl. ¶ 389, and that the knowledge or recklessness of other senior employees and managers concerning the reimbursement scheme is also imputed to Organogenesis, *see* Am.

Compl. ¶ 390.

Plaintiffs also allege that "[t]he sale of Affinity and PuraPly XT were part of Organogenesis's core operations during the Class Period, supporting an inference that Defendants knew or recklessly disregarded information concerning the true reasons for the dramatic increase in sales of these products, and the subsequent decline in Affinity sales after Affinity received an ASP." *See* Am. Compl. ¶ 391.

E. Risk Disclosures

Organogenesis's 2020 and 2021 SEC filings contained various disclosures of risks associated with the Company's business and products. For example, in its Form 10-K for the fiscal year ended December 31, 2020 (the "2020 Form 10-K"), Organogenesis stated that "[t]he rate of reimbursement and coverage for the purchase of our products by government and private insurance (including by Medicare Administrative Contractors) is subject to uncertainty," and that "even if coverage and reimbursement are provided, market acceptance of our products has been and will be adversely affected if access to coverage is administratively burdensome to obtain, use of our products is administratively burdensome, or is unprofitable for healthcare providers or less profitable than alternative treatments." *See* Defs.' Ex. 1 at 11, ECF No. 53-1. The 2020 Form 10-K also specifically informed investors that, in the physician office setting, the Medicare payment rates for all skin substitutes are updated quarterly based on manufacturer reported ASP; that "[t]he actual payment rate for skin substitutes is ASP plus 6%;" that "Medicare does not require us to report ASP for our products because they are regulated by the FDA as medical devices," but "starting in January 2022, we will be required to report ASP for all our products;" and that "[c]urrently, the local Part A/B MACs establish local payment for drugs and biologics whose ASP does not appear in the quarterly ASP file." *See* Defs.' Ex. 1 at 6. The 2020 Form

10-K also identified as factors "that may negatively affect our operating results," *inter alia*, "the rate of reimbursement for purchases of our products by government and private insurers," "any change in Medicare payment policy which provides a competitive advantage to our competitor's products," and "whether our products or our competitors' products are granted pass-through reimbursement status or included in the 'bundled' reimbursement structure." *See* Defs.' Ex. 1 at 9. The Company made similar disclosures in its Form 10-K for the fiscal year ended December 31, 2021. *See* Defs.' Ex. 2 at 6, 9-10, ECF No. 53-2.

II. Procedural Background

On December 10, 2021, Gergely Somogyi filed a Class Action Complaint alleging violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. *See* ECF No. 1. By Memorandum and Order dated August 25, 2022, Magistrate Judge Marcia M. Henry granted Donald Martin Meyer's motion for appointment as lead plaintiff and for appointment of Kessler Topaz Meltzer & Check, LLP as lead counsel. *See generally* ECF No. 25.

On October 24, 2022, Plaintiffs filed the Amended Complaint. *See* ECF No. 34.

On December 23, 2022, Defendants filed a letter motion seeking a pre-motion conference in anticipation of filing a motion to dismiss. *See* ECF No. 39. On January 6, 2023, Plaintiffs filed a letter in response to the December 23, 2022 letter motion. *See* ECF No. 40. On January 27, 2023, the Court held a pre-motion conference. *See* ECF No. 43. On May 30, 2023, Defendants filed the instant Motion to Dismiss the Amended Complaint pursuant to Rules 8(a), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure and Section 101(b) of the PSLRA, which Plaintiffs oppose. *See* ECF Nos. 52-56.

On February 20, 2024, oral argument was held on the instant motion. *See* docket entry dated February 20, 2024; *see also* Transcript of February 20, 2024 Oral Argument ("Tr."), ECF

No. 59.

STANDARD OF REVIEW

To survive dismissal for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Matson v. Bd. of Educ. of City Sch. Dist. of N.Y.*, 631 F.3d 57, 63 (2d Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The Court must "accept all 'well-pleaded factual allegations' in the complaint as true" and "'construe all reasonable inferences that can be drawn from the complaint in the light most favorable to the plaintiff.'" *Lynch v. City of N.Y.*, 952 F.3d 67, 74-75 (2d Cir. 2020) (first quoting *Iqbal*, 556 U.S. at 679; then quoting *Arar v. Ashcroft*, 585 F.3d 559, 567 (2d Cir. 2009)). However, "labels and conclusions" or "formulaic recitation[s] of the elements of a cause of action will not do," and dismissal is proper where "the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S. at 555, 558. A court is not "bound to accept conclusory allegations or legal conclusions masquerading as factual conclusions." *See Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (quotation omitted); *see also Iqbal*, 556 U.S. at 678 (noting that a court is "not bound to accept as true a legal conclusion couched as a factual allegation" (quoting *Twombly*, 550 U.S. at 555)); *Ruston v. Town Bd. for Town of Skaneateles*, 610 F.3d 55, 59 (2d Cir. 2010) (noting that "factual allegations must be sufficient to support necessary legal conclusions"). "In considering a motion to dismiss for failure to state a claim, '[a] district court is normally required to look only to the allegations on the face of the complaint,'" though "[it] may consider documents that 'are

attached to the complaint,' 'incorporated in it by reference,' 'integral' to the complaint, or the proper subject of judicial notice." *United States v. Strock*, 982 F.3d 51, 63 (2d Cir. 2020) (quoting *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007)).

A complaint alleging securities fraud must also satisfy the heightened pleading requirements set forth in Rule 9(b) and the PSLRA. *See Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012). Under Rule 9(b), a plaintiff alleging fraud "must state with particularity the circumstances constituting fraud." *See* Fed. R. Civ. P. 9(b). To satisfy this requirement, "a plaintiff must: '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 167 (2d Cir. 2021) (quoting *Anschutz*, 690 F.3d at 108). "The PSLRA expanded on the Rule 9(b) standard, requiring that 'securities fraud complaints specify each misleading statement; that they set forth the facts on which a belief that a statement is misleading was formed; and that they state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Anschutz*, 690 F.3d at 108 (alteration accepted) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005)); *see also* 15 U.S.C. § 78u-4(b)(1), (2).

DISCUSSION

For the reasons set forth below, the Amended Complaint is dismissed in its entirety.

I. Count I is Dismissed for Failure to State a Claim

Plaintiffs have failed to adequately plead that any Defendant made an actionable misstatement or omission and have failed to adequately plead scienter. Accordingly, Count I must be dismissed for failure to state a claim.

A. Applicable Law

Section 10(b) provides:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange -- [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b) (footnote omitted).

Rule 10b-5 provides:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
>
> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

"To state a claim for securities fraud under these provisions a plaintiff must allege that each defendant (1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which the plaintiff relied, and (5) that the plaintiff's reliance was the proximate cause of its injury." *In re Synchrony Fin. Sec. Litig.*, 988 F.3d at 167 (quoting *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 100 (2d Cir. 2015)).[9]

[9] Here, Defendants challenge Count I on the grounds that the Amended Complaint fails to plead

"[T]o be actionable under Section 10(b) and Rule 10b-5, the alleged misstatement or omission must be material." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 572 (S.D.N.Y. 2014) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)), *aff'd*, 604 F. App'x 62 (2d Cir. 2015). "At the pleading stage, a plaintiff satisfies the materiality requirement of Rule 10b-5 by alleging a statement or omission that a reasonable investor would have considered significant in making investment decisions." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 161 (2d Cir. 2000) (citing *Basic*, 485 U.S. at 231). Assessing materiality is "a fact-specific inquiry." *See ECA & Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.* ("*ECA*"), 553 F.3d 187, 197 (2d Cir. 2009).

Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). "Just because 'a reasonable investor would very much like to know a fact' does not create any obligation to speak up." *Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 353 (2d Cir. 2022) (alteration accepted) (quoting *Dalberth v. Xerox Corp.*, 766 F.3d 172, 183 (2d Cir. 2014)). Rather, "[d]isclosure is necessary only if there is a duty to disclose or 'when necessary to make statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* (quoting *Kleinman v. Elan Corp.*, 706 F.3d 145, 153 (2d Cir. 2013)); *see also DeKalb Cnty. Pension Fund v. Allergan PLC*, No. 23-59, 2024 WL 677081, at *1 (2d Cir. Feb. 20, 2024). "[T]here must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic*, 485 U.S. at 231-32 (quoting *TSC Indus., Inc. v.*

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any actionable misstatement or omission and fails to plead scienter. *See* Defs.' Br. at 8; *see also* Tr. at 16.

Northway, Inc., 426 U.S. 438, 449 (1976)). "Where allegedly undisclosed material information is in fact readily accessible in the public domain, the Second Circuit has found that a defendant may not be held liable for failing to disclose this information." *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 377 (E.D.N.Y. 2003) (citing, *inter alia*, *Seibert v. Sperry Rand Corp.*, 586 F.2d 949, 952 (2d Cir. 1978)).

"It is axiomatic that companies 'do not have a duty to disclose uncharged, unadjudicated wrongdoing.'" *Fogel v. Vega*, 759 F. App'x 18, 24 (2d Cir. 2018) (quoting *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014)). The critical consideration "in determining whether a corporation must disclose mismanagement or uncharged criminal conduct is whether 'the alleged omissions are sufficiently connected to defendants' existing disclosures to make those public statements misleading.'" *See In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 403 (S.D.N.Y. 2016) (ellipsis omitted) (quoting *In re Marsh & McLennan Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 469 (S.D.N.Y. 2006)); *see also Arora v. HDFC Bank Ltd.*, 671 F. Supp. 3d 305, 316 (E.D.N.Y. 2023); *Gray v. Alpha & Omega Semiconductor Ltd.*, No. 20-CV-02414, 2021 WL 4429499, at *9 n.4 (S.D.N.Y. Sept. 27, 2021); *In re FBR Inc. Sec. Litig.*, 544 F. Supp. 2d 346, 358 (S.D.N.Y. 2008). As courts have noted, "[t]he requisite connection triggering a duty to disclose uncharged wrongdoing arises in three circumstances: (1) when a corporation puts the reasons for its success at issue, but fails to disclose that a material source of its success is the use of improper or illegal business practices; (2) when a defendant makes a statement that can be understood, by a reasonable investor, to deny that the illegal conduct is occurring; and (3) when a defendant states an opinion that, absent disclosure, misleads investors about material facts underlying that belief." *See In re Virtus Inv. Partners, Inc. Sec. Litig.*, 195 F. Supp. 3d 528, 536 (S.D.N.Y. 2016) (quotations omitted); *see also In re Teva Sec.*

Litig., 671 F. Supp. 3d 147, 211-12 (D. Conn. 2023).

"[E]xpressions of puffery and corporate optimism do not give rise to securities violations." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). Statements are considered expressions of puffery when they are "too general to cause a reasonable investor to rely upon them." *See City of Pontiac Policemen's & Firemen's Ret. Sys.*, 752 F.3d at 183.

To adequately plead scienter, a complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *See* 15 U.S.C. § 78u-4(b)(2)(A). "The requisite state of mind in a section 10(b) and Rule 10b-5 action is an intent 'to deceive, manipulate, or defraud.'" *ECA*, 553 F.3d at 198 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007)). "To qualify as 'strong' . . . an inference of scienter must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. "The strength of an inference cannot be decided in a vacuum," and "[t]o determine whether the plaintiff has alleged facts that give rise to the requisite 'strong inference' of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 323-24. "[T]he court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically." *Id.* at 326.

"The requisite scienter can be established by alleging facts to show either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *ECA*, 553 F.3d at 198.

"In order to raise a strong inference of scienter though 'motive and opportunity' to defraud," a plaintiff must allege that a defendant "'benefitted in some concrete and personal way from the purported fraud.'" *Id.* (quoting *Novak v. Kasaks*, 216 F.3d 300, 307-08 (2d Cir. 2000)).

"General allegations that the defendants acted in their economic self-interest are not enough." *Ganino*, 228 F.3d at 170. "Motives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute 'motive' for purposes of this inquiry. Rather, the 'motive' showing is generally met when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit." *ECA*, 553 F.3d at 198 (citations omitted).

Unusual insider sales at the time of alleged misstatements or omissions may permit an inference of scienter. *See In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 74 (2d Cir. 2001); *see also In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009) (noting that "the mere fact that insider stock sales occurred does not suffice to establish scienter" and that "to satisfy this element, Plaintiffs must establish that the sales were 'unusual' or 'suspicious.'" (alteration accepted) (quotation omitted)). "Factors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change in volume of insider sales, and the number of insiders selling." *In re Scholastic Corp. Sec. Litig.*, 252 F.3d at 74-75. Ordinarily, "[t]rades made pursuant to a Rule 10b5-1 trading plan do not give rise to a strong inference of scienter." *See In re Lululemon Sec. Litig.*, 14 F. Supp. 3d at 585; *see also Woolgar v. Kingstone Cos.*, 477 F. Supp. 3d 193, 236 (S.D.N.Y. 2020). However, the United States Court of Appeals for the Second Circuit has noted that "[w]hen executives enter into a trading plan during the Class Period and the Complaint sufficiently alleges that the purpose of the plan was to take advantage of an inflated stock price, the plan provides no defense to scienter allegations." *See Emps.' Ret. Sys. of Gov't of the Virgin Islands v. Blanford*, 794 F.3d 297, 309 (2d Cir. 2015).

As an alternative to establishing scienter through allegations regarding motive and

opportunity, a plaintiff can "raise a strong inference of scienter under the 'strong circumstantial evidence' prong, 'though the strength of the circumstantial allegations must be correspondingly greater' if there is no motive." *See ECA*, 553 F.3d at 198-99 (quoting *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001)). "Recklessness is sufficient to establish scienter only if the defendants' actions represent 'an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'" *Gregory v. ProNAi Therapeutics Inc.*, 757 F. App'x 35, 37 (2d Cir. 2018) (quoting *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000)).

"At least four circumstances may give rise to a strong inference of the requisite scienter: where the complaint sufficiently alleges that the defendants (1) 'benefitted in a concrete and personal way from the purported fraud'; (2) 'engaged in deliberately illegal behavior'; (3) 'knew facts or had access to information suggesting that their public statements were not accurate'; or (4) 'failed to check information they had a duty to monitor.'" *ECA*, 553 F.3d at 199 (quoting *Novak*, 216 F.3d at 311).

"Where a defendant is a corporation," a plaintiff must "plead[] facts that give rise to a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter." *Jackson v. Abernathy*, 960 F.3d 94, 98 (2d Cir. 2020) (quotation omitted). "In exceedingly rare instances, a statement may be so dramatic that collective corporate scienter may be inferred." *Id*. at 99 (quotation omitted).

B. Plaintiffs Have Failed to Allege an Actionable Misstatement or Omission

Plaintiffs allege in the Amended Complaint that various statements made by Defendants during the Class Period are actionable under Section 10(b) and Rule 10b-5. *See* Am. Compl. ¶¶ 241-346. In substance and in summary, Plaintiffs allege that these statements are actionable

because Defendants failed to disclose: (1) that "the demand for Affinity and PuraPly XT was being engineered by a concerted scheme by Defendants to incentivize physicians to purchase Affinity and PuraPly XT based on the spread" and that "the rapid increase in Affinity and PuraPly XT sales in the physician office channel had been driven by the Company's marketing of this temporary reimbursement spread using Company-supplied marketing materials;" (2) that "Organogenesis focused its illicit marketing efforts for Affinity and PuraPly XT in the physician office channel in areas where the regional MAC reimbursement rates were highest, and where the MACs did not require physicians to submit physical invoices from the Company;" (3) that "once these products had an established ASP, demand for these products would diminish and revenue for these products would decrease or grow at a much slower rate;" and (4) that "Organogenesis had a temporary competitive edge that was dependent on its Medicare Reimbursement Scheme." *See, e.g.*, Am. Compl. ¶¶ 247-50; *see also* Am. Compl. ¶ 318.

With respect to the alleged actionable statements, Defendants argue, *inter alia*, that "[w]ith Defendants' clear cautionary language in SEC filings, conferences, and earnings calls, no reasonable investor could have been misled to believe that Organogenesis' products receiving an ASP would have no negative effect on revenue;" that "Defendants' statements about revenue and sales are not properly pleaded as false and are far too general and removed from the supposed marketing scheme to trigger any duty for Defendants to disclose that alleged scheme;" and that "the remainder of the Plaintiffs' misrepresentation allegations are easily disposed of under black letter law that general statements about compliance, statements reporting historical revenue, corporate optimism, puffery, opinion, and forward-looking statements accompanied by meaningful cautionary language are all not actionable." *See* Defs.' Br. at 2, 11.

Here, Plaintiffs have failed to allege any actionable misstatement or omission because the

statements at issue are not sufficiently alleged to be false and are not sufficiently alleged to be misleading such that they would give rise to a duty to disclose the alleged marketing scheme.

Although Plaintiffs describe all of the alleged actionable statements as being "false or misleading," *see, e.g.*, Am. Compl. ¶ 240, Plaintiffs do not allege facts demonstrating that any alleged actionable statement was objectively false. For example, the Amended Complaint does not contain any allegations that financial results stated by Defendants were inaccurate or that certain factors identified by Defendants did not contribute to the Company's growth. *See generally* Am. Compl.; *see also* Pls.' Br. at 17 (noting that "Plaintiffs do not challenge Organogenesis's financial results").

In the absence of allegations demonstrating that any alleged actionable statement was objectively false, the Court considers whether the alleged actionable statements were misleading. The Court concludes that they were not.

As an initial matter, many of the alleged actionable statements address only in general terms the Company's growth, financial performance, ability to compete, and/or compliance and are too general and too far removed from the alleged marketing scheme to trigger a duty to disclose any such scheme and/or are inactionable because they are expressions of puffery and corporate optimism. *See, e.g.*, Am. Compl. ¶¶ 256 ("we are a very compliant company, and we are the gold standard of compliance"), 265 ("we believe our operating and financial performance is a direct result of the strong execution of our growth and profitability strategy and the dedication of our employees to our customers and the patients they serve"), 286 ("Our better-than-expected growth in Q1 reflects a continuation of the key drivers of our growth strategy, including the benefits of our comprehensive portfolio of products, the investments that we've made to broaden our reach by expanding our sales force and the strong execution of our

commercial strategy, focusing on leveraging multiple channels, new product introductions and brand loyalty."), 291 ("we definitely feel that there's a margin -- a market shift in our favor"), 312 ("Our year-to-date performance and progress against our strategic priorities is a direct result of the strength of our organization and the dedication of our employees."), 328 ("our comprehensive portfolio of products is a key competitive advantage for Organogenesis and continues to be a primary driver of our impressive growth in recent years"), 337 ("Organogenesis is well-positioned to manage through the near-term operating environment challenges and achieve strong, long-term growth.").

The remaining alleged actionable statements – those in which Defendants specifically discuss Affinity and PuraPly XT's performance and Organogenesis's "office channel" strategy – present a closer question but also do not give rise to a duty to disclose the alleged marketing scheme because those statements do not detail any specific marketing strategies or efforts with respect to Affinity and PuraPly XT, do not suggest that the undisclosed improper activity alleged by Plaintiffs was not occurring, do not suggest that reimbursement status did not affect Affinity and PuraPly XT's success, and do not otherwise conceal the importance of reimbursement with respect to those products. *See, e.g.*, Am. Compl. ¶¶ 242 ("we launched PuraPly XT and Affinity in the midst of a crisis and both have exceeded our expectations" and the "office space business grew even faster than we thought"), 254 ("one of the reasons we've moved into the office and really put a major emphasis on the office-based setting is it's a different reimbursement model than the outpatient model"), 266 ("we've also accelerated our office growth strategy with PuraPly"), 283 ("the increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product" and "the continued increase in

PuraPly revenue in the year ended December 31, 2020 was due to the expanded sales forces, expanded product offerings, and increased sales to existing and new customers.”), 288 (“we believe [our Q1 results] reflects the strong execution of the strategy to navigate the loss of PuraPly pass-through status and the corresponding headwinds related to this change in reimbursement”), 289 (“We have been working on penetrating the office market primarily with channel-specific product offerings” and “continue to expand the number of customers in the office channel, and we are seeing increasing utilization of our products from existing customers.”).

Moreover, as Defendants note and as set forth above, certain of the Company’s SEC filings contained risk disclosures addressing fluctuations in the rate of reimbursement of the Company’s products as well as risks to revenue associated with the reimbursement of the Company’s products. *See* Defs.’ Br. at 4-6, 10-11; Defs.’ Ex. 1 at 6, 9, 11; Defs.’ Ex. 2 at 6, 9-10. These disclosures warned investors about the potential impact that changes in reimbursement for Affinity and PuraPly XT would have on the Company’s financial performance as well as the Company’s ability to compete in the market. *See In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d at 377.

Plaintiffs have failed to allege any actionable misstatement or omission and Count I must therefore be dismissed.[10]

C. Plaintiffs Have Failed to Establish a Strong Inference of Scienter

Count I must also be dismissed for the additional reason that Plaintiffs have failed to adequately plead scienter with respect to any Defendant. Plaintiffs assert that the Amended

[10] Even if one or more of the alleged misstatements or omissions could be deemed to be an actionable misstatement or omission, Count I nevertheless would be dismissed for failure to establish a strong inference of scienter, as discussed further below.

Complaint pleads facts supporting a strong inference of Defendants' scienter through "both motive and strong circumstantial evidence of recklessness or conscious misbehavior." *See* Pls.' Br. at 25. The Court disagrees.

1. Motive and Opportunity

With respect to motive and opportunity, Plaintiffs point to the Amended Complaint's allegations regarding Defendant Gillheeney's sales of Organogenesis stock, the Company's SPO, and Defendants' need to offset revenue declines from the loss of PuraPly's pass-through status. *See* Pls.' Br. at 32-39.

Here, Defendant Gillheeney's stock sales were not unusual or suspicious such that they give rise to a strong inference of scienter. As an initial matter, the parties do not dispute that all of Defendant Gillheeney's alleged sales were made pursuant to 10b5-1 plans. *See, e.g.*, Am. Compl. ¶¶ 356, 359, 363. And, although the Amended Complaint alleges that Defendant Gillheeney entered into the relevant 10b5-1 plans during the Class Period, the Amended Complaint does not adequately allege that the purpose of the plans was to take advantage of an inflated stock price. *See Emps.' Ret. Sys. of Gov't of the Virgin Islands*, 794 F.3d at 309. That the stock sales were made pursuant to 10b5-1 plans undercuts Plaintiffs' scienter argument here. *See Ark. Pub. Emps. Ret. Sys.*, 28 F.4th at 356 n.4; *see also City of Warren Police & Fire Ret. Sys. v. Foot Locker, Inc.*, 412 F. Supp. 3d 206, 226-27 (E.D.N.Y. 2019).

Moreover, Defendant Gillheeney's sales were not otherwise unusual or suspicious in timing or amount. Even assuming that Plaintiffs' calculation of the percentages of shares sold is correct, such percentages of shares sold fail to establish a strong inference of scienter. *See In re CRM Holdings, Ltd. Sec. Litig.*, No. 10-CV-00975, 2012 WL 1646888, at *23-24 (S.D.N.Y. May 10, 2012). Plaintiffs also fail to demonstrate that the timing of Defendant Gillheeney's sales was

calculated to maximize the personal benefit from undisclosed inside information. *See City of Taylor Gen. Emps. Ret. Sys. v. Magna Int'l Inc.*, 967 F. Supp. 2d 771, 800 (S.D.N.Y. 2013). Indeed, various of Defendant Gillheeney's sales pre-dated and post-dated the alleged actionable statements by several weeks, *see* Am. Compl. ¶¶ 354, 357, and Defendant Gillheeney's last alleged sale occurred more than two months prior to the end of the Class Period, *see* Am. Compl. ¶ 361.

Further, Plaintiffs do not allege that Defendant Francisco, or any other Organogenesis executive, sold any shares in the Company during the Class Period, which weighs against an inference of scienter. *See Wyche v. Advanced Drainage Sys., Inc.*, 710 F. App'x 471, 473 (2d Cir. 2017); *see also Russo v. Bruce*, 777 F. Supp. 2d 505, 517 (S.D.N.Y. 2011).

Nor can Plaintiffs establish motive and opportunity through allegations of generalized "motives possessed by virtually all corporate insiders," *see Novak*, 216 F.3d at 307, including the desire to offset an anticipated decrease in revenue, *see* Pls.' Br. at 39 (arguing that Defendants were motivated to offset PuraPly's pass-through revenue and citing Am. Compl. ¶¶ 97-106, 112-52), or the desire to raise capital, *see* Am. Compl. ¶ 365 (alleging that Organogenesis sold shares of its common stock in the SPO while the alleged marketing scheme was ongoing).

Plaintiffs have failed to sufficiently allege a strong inference of scienter through motive and opportunity.

2. Circumstantial Evidence

With respect to circumstantial evidence of conscious misbehavior or recklessness, Plaintiffs point to the Amended Complaint's allegations purportedly demonstrating that Defendants knew or had access to information contradicting their statements; that Defendants engaged in deliberately illegal behavior; and that Defendants recklessly disregarded red flags,

including the Company's increase in revenue following the loss of PuraPly's pass-through status and the decline in Affinity sales after it received an ASP. *See* Pls.' Br. at 25-32.

Here, assessed holistically, the allegations in the Amended Complaint do not demonstrate strong circumstantial evidence of conscious misbehavior or recklessness.

As an initial matter, Plaintiffs do not sufficiently allege that the Individual Defendants knew or had access to information contradicting their public statements. Notably, the Amended Complaint fails to identify any specific reports or statements that were contradictory to the Individual Defendants' statements or any specific instances in which the Individual Defendants received information that was contrary to their public statements. *See Novak*, 216 F.3d at 309; *Plumbers & Steamfitters Loc. 773 Pension Fund v. Canadian Imperial Bank of Com.*, 694 F. Supp. 2d 287, 299 (S.D.N.Y. 2010). Plaintiffs' general allegations regarding the Individual Defendants' roles at the Company and access to the Power BI system and regarding marketing spreadsheets, *see, e.g.*, Am. Compl. ¶¶ 367, 373, 375, 378; *see also* Pls.' Br. at 25, are insufficient to demonstrate that the Individual Defendants knew or should have known they were misstating or omitting material facts. And, the Individual Defendants' statements *themselves* – including statements about "thoughtfully" and "strategically" launching PuraPly XT and Affinity, respectively, in certain areas, *see* Am. Compl. ¶ 367 – do not suggest that the Individual Defendants received information about the alleged true drivers of Affinity and PuraPly XT sales. Plaintiffs' assertion to the contrary fails to account for more compelling inferences – including that the Individual Defendants believed that the sales growth was due to factors unrelated to any improper activity.

Plaintiffs' reliance on the FEs' statements to demonstrate that the Individual Defendants knew or had access to information contradicting their public statements is unavailing. Indeed,

the FEs' statements fail to identify any information that directly contradicted the alleged actionable statements and fail to connect the Individual Defendants to any information indicating that the Company was engaging in the alleged marketing scheme. Notably, the Amended Complaint does not allege that any FE had direct discussions with or attended any meeting with either of the Individual Defendants. *See generally* Am. Compl.; *see also In re Turquoise Hill Res. Ltd. Sec. Litig.*, No. 13-CV-08846, 2014 WL 7176187, at *7 (S.D.N.Y. Dec. 16, 2014); *Maloney v. Ollie's Bargain Outlet Holdings, Inc.*, 518 F. Supp. 3d 772, 780-81 (S.D.N.Y. 2021). Although Plaintiffs highlight FE-6's statement that FE-6 "wrote a letter to Gillheeney and explained that Gillheeney was placing too much pressure on the sales force to grow sales, and that this pressure had led the sales representatives to engage in misconduct," the Amended Complaint does not allege that Defendant Gillheeney saw or reacted to FE-6's letter, that the letter specifically mentioned the alleged marketing scheme, or that Defendant Gillheeney was obligated to rely on FE-6's concerns. *See* Am. Compl. ¶ 381. And, FE-6's statement that FE-6 reported the Company's "illegal conduct" to an unnamed Director of Compliance does not establish that this information was ultimately reported to either Individual Defendant. *See* Am. Compl. ¶ 381.[11] Further, the allegation that FE-4 "recalled that sales representatives received under the radar direction from Organogenesis management that they should sell Affinity and PuraPly XT on the spread while there was no ASP," *see* Am. Compl. ¶ 188, does not identify either of the Individual Defendants as the "Organogenesis management" at issue. Taken as a whole, the FE accounts do not sufficiently demonstrate that the Individual Defendants knew or

[11] Similarly, Plaintiffs' allegations based on FE-6's account regarding retaliation, *see, e.g.*, Am. Compl. ¶ 381, are insufficiently particularized and, in any event, fail to demonstrate that the Individual Defendants received information regarding the alleged retaliation or were otherwise involved in the alleged retaliation.

had access to information contradicting their public statements.

Nor do the FE accounts sufficiently demonstrate that either Individual Defendant engaged in deliberately illegal behavior sufficient to give rise to an inference of scienter and the Amended Complaint does not otherwise sufficiently allege that either Individual Defendant deliberately engaged in or even knowingly sanctioned any illegal behavior. Even assuming *arguendo* that Plaintiffs have sufficiently pled that the alleged marketing scheme was illegal, Plaintiffs have failed to connect the Individual Defendants to the scheme.

Plaintiffs also have failed to sufficiently allege that the Individual Defendants acted recklessly. Plaintiffs assert that Defendants should have been alerted to the alleged marketing scheme by the fact that "Organogenesis's revenue increased following the loss of PuraPly's pass-through status" and by "the dramatic decline in Affinity sales after it received an ASP." *See* Pls.' Br. at 31-32 (emphasis omitted). Plaintiffs' allegations, however, do not demonstrate that the Individual Defendants engaged in conduct that was highly unreasonable and that represented an extreme departure from the standards of ordinary care. *See In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d at 39. And, Plaintiffs fail to account for more compelling inferences – including that the Individual Defendants believed that the changes in revenue and sales were the result of factors referenced in the Company's risk disclosures.

Plaintiffs' allegations that Affinity and PuraPly XT sales were part of Organogenesis's core operations during the Class Period do not save Plaintiffs' scienter theory. Although the Second Circuit does not appear to have expressly determined whether the core operations doctrine survives as a viable theory of scienter following the enactment of the PSLRA, *see Frederick v. Mechel OAO*, 475 F. App'x 353, 356 & n.5 (2d Cir. 2012), courts have held that the doctrine can provide supplemental support for allegations of scienter, even if it cannot establish

scienter independently, *see City of Omaha Police & Fire Ret. Sys. v. Evoqua Water Techs. Corp.*, 450 F. Supp. 3d 379, 424 (S.D.N.Y. 2020) (collecting cases); *see also New Orleans Emps. Ret. Sys. v. Celestica, Inc.*, 455 F. App'x 10, 14 n.3 (2d Cir. 2011). Here, Plaintiffs' allegations regarding core operations, standing alone, are insufficient to establish the Individual Defendants' scienter.

Plaintiffs have failed to allege strong circumstantial evidence of conscious misbehavior or recklessness sufficient to demonstrate scienter.

* * *

Plaintiffs also have failed to adequately plead corporate scienter.

Plaintiffs do not plead facts that give rise to a strong inference that someone whose intent could be imputed to the Company acted with the requisite scienter. *See Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008). As set forth above, Plaintiffs have failed to establish a strong inference of scienter as to the Individual Defendants. Further, the allegations in the Amended Complaint regarding unidentified management or other non-party Organogenesis employees are not sufficiently particularized and do not establish any scienter that could be imputed to the Company. Nor do Plaintiffs allege any statement "so 'dramatic' that collective corporate scienter may be inferred." *See Jackson*, 960 F.3d at 99 (quoting *Dynex*, 531 F.3d at 195-96).

* * *

Plaintiffs have failed to adequately plead that any Defendant made an actionable misstatement or omission and have failed to adequately plead scienter. Accordingly, Count I is dismissed for failure to state a claim.[12]

[12] Plaintiffs argue that Defendants violated their SEC disclosure obligations under Regulation

II. Count II is Dismissed for Failure to State a Claim

In light of the dismissal of Count I, Count II must be dismissed for failure to state a claim.

In Count II, Plaintiffs bring claims against the Individual Defendants under Section 20(a) of the Exchange Act, which provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable (including to the Commission in any action brought under paragraph (1) or (3) of section 78u(d) of this title), unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a).

"To establish a prima facie case of control person liability, a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007).

Because Plaintiffs have failed to adequately plead a primary violation of the Exchange Act, Count II must also be dismissed.

III. Plaintiffs are Denied Leave to Further Amend

Here, dismissal is without leave to amend given that the complaint has already been

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S-K, 17 C.F.R. § 229.303 ("Item 303"). *See* Pls.' Br. at 24. However, because Plaintiffs have failed to sufficiently allege scienter, the alleged actionable statements do not give rise to liability under Item 303. *See In re Gen. Elec. Sec. Litig.*, 844 F. App'x 385, 387 (2d Cir. 2021). Plaintiffs' additional argument – set forth in a footnote in their opposition briefing – that "Defendants' scheme rendered their statements during the Class Period materially false or misleading" and that "[t]his conduct also constituted a fraudulent scheme in violation of Rules 10b-5(a) and (c)," *see* Pls.' Br. at 8 n.5 (citing Am. Compl. ¶¶ 36, 420), similarly fails in light of Plaintiffs' failure to establish scienter. *See Plumber & Steamfitters Loc. 773 Pension Fund v. Danske Bank A/S*, 11 F.4th 90, 105 (2d Cir. 2021).

amended once; that Plaintiffs were apprised of the pleading defects in the Amended Complaint by way of Defendants' request for a pre-motion conference, *see* ECF No. 39, and did not then seek leave to amend, stating in their response to Defendants' request that Plaintiffs "do not currently seek leave to amend but reserve their right to amend in response to any motion to dismiss," *see* ECF No. 40 at 3 n.5; that Plaintiffs were further apprised of the pleading defects by way of Defendants' motion to dismiss, *see* ECF Nos. 52, 54, and did not in response seek leave to amend, stating only in their opposition briefing that "[i]f the Court grants any part of Defendants' motion, Plaintiffs respectfully request leave to amend," *see* Pls.' Br. at 40; that Plaintiffs have not identified in briefing and did not identify at oral argument any particular allegations Plaintiffs might add if granted leave to amend, *see generally* Pls.' Br.; *see also* Tr. at 40-41; and that on the record before the Court, there is no indication that Plaintiffs could provide additional allegations that might cure the defects set forth above and lead to a different result. *See Gallop v. Cheney*, 642 F.3d 364, 369-70 (2d Cir. 2011); *Gregory*, 757 F. App'x at 39.[13]

CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss, ECF No. 52, is GRANTED and the Amended Complaint, ECF No. 34, is DISMISSED.

The Clerk of Court is directed to enter judgment accordingly and to close this case.

SO ORDERED.

/s/ Diane Gujarati
DIANE GUJARATI
United States District Judge

Dated: March 29, 2024
Brooklyn, New York

[13] Defendants oppose further amendment. *See* Defs.' Reply at 20; Tr. at 41-42.